



Exhibit A

PATENT
PC8618JTJ

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

JUN 28 2004

IN RE APPLICATION OF: :

WILLIAM J. CURATOLO ET AL.

EXAMINER: H. LEE

TECH CENTER 1600/2900

SERIAL NO.: 08/235,069 :

ART UNIT: 1803

FILED: APRIL 29, 1994 :

FOR: METHOD OF ADMINISTERING :

AZITHROMYCIN :

Hon. Commissioner of Patents and Trademarks
Washington, D.C. 20231

Sir:

I hereby certify that this
correspondence is being
deposited with the United States
Postal Service as First Class mail
in an envelope addressed to:
Commissioner of Patents and
Trademarks, Washington, D.C.
20231, on this 24th day of

January 19 95
By *Michael J. Galvez*

DECLARATION 1 UNDER 37 CFR 1.132

I, William J. Curatolo, do hereby declare as follows:

1. I received a Bachelor of Engineering in Electrical Engineering from Manhattan College, a Master of Arts in Biology from the State University of New York at Binghamton, and a Doctor of Philosophy degree in Biochemistry/Biophysics from Boston University. I was a Postdoctoral Fellow in the Departments of Biology and Chemistry at the Massachusetts Institute of Technology from 1977-1979. I was a Staff Scientist in the Molecular Biophysics Section in the Francis Bitter National Magnet laboratory at the Massachusetts Institute of Technology from 1979-1983. I have worked for twelve years in the Pharmaceutical Research and Development Department at Pfizer Central Research as a drug formulator and manager of drug formulators. I am currently an Assistant Director with responsibility for oral drug delivery, controlled release forms and biopharmaceutics. I am an elected Fellow of the American Association of Pharmaceutical Scientists. The designation "Fellow" recognizes exceptional technical expertise in Pharmaceuticals and Drug Delivery.

2. Azithromycin is an azalide antibiotic with chemical, physical, biological and pharmaceutical properties quite different from other antibiotics, including

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erythromycin. Further, azithromycin is 326 times more stable than erythromycin in solution (Fiese and Steffen, Journal of Antimicrobial Chemotherapy, 1990, 25, Suppl. A, 39-47, a copy of which is attached as Exhibit A). Azithromycin differs structurally from erythromycin by having a 15-membered ring rather than a 14-membered ring. Further, azithromycin lacks the C-9 ketone of erythromycin, having instead a (methyl)amino methylene group between the C-8 and C-10 carbons. As a result of its unique chemical structure, azithromycin has an exceptionally long elimination half-life (69 hours in humans), which permits successful therapy with once-daily dosing for one to five days. By contrast, erythromycin has an approximately two hour elimination half-life in humans, and must be dosed multiple times per day for many days. These elimination half-life distinctions reflect different sensitivities to metabolic enzymes in the human body, and are also reflective of differences in the chemical labilities of these two distinct antibiotics.

3. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

DATE:

Jan 23, 1996

William J. Curatolo
WILLIAM J. CURATOLO